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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/897,351	07/21/97	JANJIC	N NEX61/CIP

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HM31/0608

EXAMINER	
ZITOMER, S	
ART UNIT	PAPER NUMBER
1634	7

DATE MAILED: 06/08/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
08/897,351

Applicant(s)
JANJIC et al.

Examiner
Stephanie Zitomer

Group Art Unit
1634



☒ Responsive to communication(s) filed on Jul 21, 1997

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). *ONE MONTH FOR COMPLIANCE WITH SEQUENCE RULES*

Disposition of Claim

☒ Claim(s) 1 and 2 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 2 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 & 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

Notice to comply with sequence rules

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Notice to comply with sequence rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given **ONE MONTH, or THIRTY DAYS**, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Informalities

.5 The disclosure is objected to because of the following informalities: The disclosure is not in compliance with the sequence rules because nucleotide sequences in the specification, tables and figures lack SEQ ID NO:s.

Appropriate correction is required.

Rejections under 35 USC 112, second paragraph

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claim is indefinite because it is garbled and appears to be missing a word or words at line 1.

(b) The claim is indefinite in the recitation "prolonging the residence time...in an ocular application" because "application" does not define the site of "residence".

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(c) The claim is indefinite in reciting "nucleic acid ligand" which is a general term lacking definition or specificity. The skilled practitioner in the art would not be apprised of the scope of the claimed method.

(d) The claim is indefinite because the steps of "attaching" and "administering" are *non sequitur*, having no obvious relation to one another.

Double patenting obviousness type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 and 11-13 of copending Application No. 08/447,169 in view of Toole et al. (WO 92/14843). The claimed RNA ligand differs from the 3' modified and unmodified ligands of the '169 claims in being comprised of 3' fluoro-modified nucleotides. However, Toole et al. teach 3' fluoro modified nucleic acid ligands (page 27). It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the '169 ligands with the teachings of Toole et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated to do so by the teachings of Toole et al. that such modifications increase the stability of nucleic acid ligands to nucleases and increase permeability (page 25, last paragraph).

This is a provisional obviousness-type double patenting rejection.

Conclusion

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3. The claims are free of the prior art but rejected on other grounds. Toole et al. (WO 92/14843) teach nucleic acid ligands to PDGF2 α and Janjic et al. (5,459,015) teach ligands to bFGF both of which are growth factors related to VEGF. Jakeman et al. (J. Clin. Invest. 1992) teach the angiogenesis properties of VEGF which are similar to those of bFGF. However, neither these references nor other prior art of record teach or suggest an RNA ligand to VEGF comprised of 2' fluoro modified nucleotides or a method for administering a nucleic acid ligand complexed with a high molecular weight compound to the eye.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephanie W. Zitomer, Ph.D.
June 8, 1998

STEPHANIE W. ZITOMER
PRIMARY EXAMINER